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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/728,577

12/05/2003

Scott A. Burton

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01/07/2010

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

01/07/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/728,577	<b>Applicant(s)</b> BURTON ET AL.	
	<b>Examiner</b> BLESSING M. FUBARA	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-26,60 and 75-121 is/are pending in the application.
- 4a) Of the above claim(s) 9,10,20,79-81,85-87,95,96,102 and 108-121 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 2-8,11-19,21-26,60,75-78,82-84,88-94,97-101 and 103-107 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/23/09 &amp; 7/28/09</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

The examiner acknowledges receipt of IDS filed 10/23/09 and 7/28/09, amendment and remarks filed 10/23/200. Claims 77, 79, 82 and 85 are amended. Claims 2-26, 60 and 75-121 are pending.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2-8, 11-19, 21-26, 60, 75-78, 82-84, 88-94, 97-101 and 103-107 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

4. Claims 77 and 82 are amended to say that a “polymer composition is disposed thereon” and the specification as originally filed does not envision disposing a polymer composition. Applicant has not pointed to any section of the original specification that provides support for disposing a polymer composition thereon and the examiner cannot find section of the specification that provides the support.

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5. Claims 2-8, 11-19, 21-26, 60, 75-78, 82-84, 88-94, 97-101 and 103-107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The recitation in amended claims 77 and 82 that a "polymer composition is disposed thereon" is unclear and it is confusing as to on what surface the polymer composition is disposed on. For examination purposes, the claims are examined as composition that comprises a substrate and polymer composition.

7.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 2-8, 11-19, 21-26, 60, 75-78, 82-84, 88-94, 97-101 and 103-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lorenz et al. (US 6,217,889).

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11. Independent claims 77 and 82 and dependent claims 26 and 107 are product by process claims. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In the present case, the claims are directed to a product and patentability of the claims is not dependent on how the product is made.

12. Lorenz discloses compositions comprising a) synthetic polymer such as polyamides, polyurethane foam and polyesters (column 4, lines 49-64), which is constituent of the creped non-woven layer of the composition in the form of film or sponges (column 4, lines 12, 13; column 6, lines 48-51; column 8, lines 37-40), b) therapeutic agents such as silver nitrate antiviral agents (column 31, line 64) or zinc oxide sunscreen actives (column 32, lines 28 and 29), c) composition may also contain cationic lathering surfactants such as fatty amines, di-fatty quaternary amines, tri-fatty quaternary amines, imidazolinium quaternary amines, monalkyl quaternary amines, cetyltrimethylammonium bromide, dialkylamidoethyl hydroxyethylmonium methosulfate and combinations thereof (column 14, lines 32-46); the composition may also contain dyes or preservatives (Example 8) and silicone antifoaming agent (column 24, line 1), d) the composition of Lorenz is an emulsion with water in oil emulsion preferred (column 23, lines 46-57) and the oils used in the emulsion are animal or plant or petroleum oils (column 23, lines 47-52), mineral oils are listed under the section of hydrophobic conditioning agents (column 20, lines 1-38). Combinations of polymers are contemplated (column 4, lines 54). Lorenz suggests that polymeric gelling agents in the form of particles can be used (column 35, lines 21-23 and

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28). The creped non woven layer of the composition is comprised of fibers, foams, scrims, etc (column 4, lines 10-47) and these non woven substrates in the form of scrims or apertured materials (column 5, lines 53-58) meet the requirement for apertured permeable substrate and polymeric fibers; the polymers in the emulsion of Lorenz comprising the cleansing component that foam or lather (column 9, lines 63-67) meet the limitations of physical expandable 21-23, 104 and 105 and since microspheres are particles, the microspheres of claims 24 and 106 read on polymer particles in the emulsion Lorenz.

13. The oil in the water in oil emulsion of Lorenz meets the requirement for the hydrophobic continuous phase of claims 77 and 82. Silver nitrate is a silver compound that meets the requirement for a silver compound bioactive agent of claims 77 and 82. The solubility of a silver compound in water of at least 0.1 gram per liter is the characteristic property of the silver compound such that the silver nitrate, a silver compound, would also have that characteristic property. Claims 78 and 83 recite the properties of the composition that would be displayed when the composition is coated on a substrate and the composition of Lorenz would also display those characteristic properties when coated on a substrate. The polyurethane form of Lorenz meets the foam of claims 21 and 103. Combinations of polymers are contemplated by Lorenz (column 4, lines 54) meeting claims 17 and 101. The quaternary amine compounds of Lorenz meet the quaternary amine compound requirements of claims 13, 14 77, 82, 88-92 and 99. The stability of the composition in claim 25 is a property that is met by the composition of Lorenz, which has not described the composition as unstable. Although Lorenz suggests that the polymer can be particles (column 35, lines 21-23 and 28), Lorenz does not specifically teach the sizes of the particles. It is known in the art that emulsions contain particles and applicant's

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specification has not declared or demonstrated that the particles sizes recited in claims 77, 82, 2-5, 88-91 provides unexpected results so that the particle sizes of these claims would be obvious over the particles of Lorenz. Claims 5, 6, 91 and 92 recite the properties of the polymer particles as being super absorbent and the polymers of Lorenz, being the same are also super absorbent. Polyurethane is recited as elastomeric polymer in claim 8 and 94, therefore, the polyurethane of Lorenz meets claims 7, 8, 93 and 94; the polyurethane also meets the hydrophilic polymer of claims 11, 12, 97 and 98. Dyes, preservatives and silicone antifoaming agent meet the additive of claims 15 and 100.

14. Claims 77 and 82 have been amended to state that the polymer composition is disposed thereon and the examiner examines the claims as having the polymer composition as part of the substrate. Lorenzen discloses polymer composition that is part of a creped non-woven layer of the composition in the form of film or sponge that further comprises therapeutic agents such as silver nitrate antiviral agents or zinc oxide sunscreen actives. Those the polymer composition that is part of the creped non-woven film or sponge meets the limitation or renders obvious the limitation.

15. While Lorenz anticipates hydrophilic polymeric particles, Lorenz is silent in the %amount of the hydrophilic polymer and the silence is an indication that any amount of the polymer can be used since compositions are made from measured amounts of components so that the ordinary skilled artisan has the capability of using amounts of the components for the composition of Lorenz that would be suitable for the intended use of the composition. Therefore, taking the teachings of Lorenz, one having ordinary skill in the art at the time the invention was made would use polymer particles in the emulsion in amounts such that the

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emulsion would be effective for the intended use of the composition. In the absence of unexpected results, the broad % amount of the polymer particles in amounts of 1-60 wt-% is not inventive over the prior art composition that is silent on the amounts.

***Response to Arguments***

16. Applicant's arguments filed 10/23/09 have been fully considered but they are not persuasive.

17. Applicant argues that the composition of Lorenz is not a wound dressing. But, the recitation of wound dressing in the preamble of the claims is the intended use of the composition and the composition of Lorenzen is capable of the intended use and examiner also notes that the composition of Lorenzen comprises creped non-woven layer.

18. Applicant argues that the polymer composition of the invention is disposed on a substrate wherein the substrates includes hydrophobic phase and the Lorenzen art does not. The examiner disagrees. The claims do not say disposing a polymer composition on a substrate where the substrate is a hydrophobic phase. Therefore, applicant is relying on limitations that are not in the claims. However, Lorenzen's creped non-woven film layer or sponge contains or carries the polymeric composition such that because the composition is part of the non-woven film or creped non-woven film or sponge, the composition meets that limitation as examined. In fact, a layer of creped non-woven film containing the polymer composition carries the composition and meets that limitation.

19. Applicant argues that hydrophobic material "is antagonistic to shedding, tending not to combine with water, or incapable of dissolving in water." But the claims do not recite hydrophobic material and a generic hydrophobic material would also have "antagonistic to



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shedding, tending not to combine with water, or incapable of dissolving in water" properties.

Also, in general creped non-woven is used with reference to fibers, which are insoluble in water.

20. Applicant also argues that the technique used to prepare the composition of Lorenzen would not result in incorporating at least a portion of anti-viral bioactive agent within the gelling agent particles. But, the claims are directed to compositions/product/article and how the composition is made does not confer patentable distinction over the prior art. Furthermore, there is nothing that says in Lorenzen that the antiviral agent is not part of the creped non-woven layer or polymeric composition.

21. Applicant states that the polyurethane foam and polyesters are materials that form the substrate and are not part of the polymer composition wherein at least a portion of the bioactive agent is incorporated within the microparticles, which is disposed on a substrate. The examiner disagrees. The composition of Lorenzen comprises a polymer which applicant has said is the substrate, and within the substrate of Lorenzen, which is the creped non-woven layer is present the active agent in the particle form.

22. The examiner has reconsidered the Lorenzen art and applicant's arguments and the arguments are not persuasive to overcome Lorenzen art.

### ***Double Patenting***

23. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

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*Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

24. Claims 2-8, 11-19, 21-26, 60, 75-78, 82-84, 88-94, 97-101 and 103-107 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 94-117; 1-4, 6-35, 37-39 and 45-50 of copending Application Nos. 10/728,439; 10/728,446 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims and the co-pending claims are directed to composition that contains bioactive silver compounds, polymer matrix, foaming agent and the composition is used as care for wounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. Claims 2-8, 11-19, 21-26, 60, 75-78, 82-84, 88-94, 97-101 and 103-107 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 5-28 of copending Application No. 10/729,114 in view of Asmus (5,270,358). The copending application discloses the composition of the examined claims except that the claims are silent as to whether the composition contains oil. But the co-pending claims contain the same polymers and the composition is used as wound dressing composition. However, Asmus discloses an emulsion that comprises the composition of the copending

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application for use in wound care. Therefore, it would have been obvious to use the composition of the co-pending application as an emulsion in wound treatment.

This is a provisional obviousness-type double patenting rejection.

***Response to Arguments***

26. Applicant's arguments filed 8/21/08 have been fully considered but they are not persuasive.

27. Applicant proposes to address the provisional obviousness-type double patenting rejection when allowable subject matter is identified. However, the rejection will continue to be made until the rejection is overcome as stated in MPEP 804 [R-5], I B, that "the "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications." As noted above, the provisional obviousness double patenting rejection is not the only rejection remaining in this examined application. Thus rejection is maintained and is not held in abeyance.

28. No claim is allowed.

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

30.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/  
Primary Examiner, Art Unit 1618